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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,428	02/28/2002	Preston Keusch	001160CIPCIPCON	4867

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/085,428

Applicant(s)

KEUSCH ET AL.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-69 is/are pending in the application.
- 4a) Of the above claim(s) 22-53 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 22 -23, drawn to lidocaine-epinephrine reservoir and a package, classified in class 206, subclass 440.
- II. Claims 24-40, 69, drawn to an electrode assembly having a crosslinked polymer reservoir containing lidocaine and epinephrine, classified in class 424, subclass 449.
- III. Claims 41-44, drawn to a irradiated crosslinked polymer reservoir, classified in class 424, subclass 486.
- IV. Claims 45-53, drawn to a method of making a reservoir with a support member, classified in class 427 subclass 331.
- V. Claims 54-68, drawn to a package electrode assembly having a working and a return electrode, classified in class 604, subclass 20.

The inventions are distinct, each from the other because of the following reasons:

Inventions III vs. I-II and IV-V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the pructs can be made without a reinforcing member or without irradiation type crosslinking.

Inventions I, II, IV and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each of the inventions has separate utility such as a I) a reservoir for storing lidocaine-epinephrine, II) IV) as ready to use devices that do not have packaging V) as an iontophoresis delivery procedure that uses a return electrode having a ion conduction reservoir. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Bernard Pike on 4-2-04 a provisional election was made without traverse to prosecute the invention of group V, claims 54-68. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-53, and 69 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

Claims 56-57, 59, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 56-57 and 69 take original percentage weights from the original specification and now add the words "up to" in front of those weight percentages creating ranges that were not previously conveyed to the reader. Thus the subject matter is regarded as new matter since it was first presented in a preliminary amendment after the filing of this application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-57, 60-66 rejected under 35 U.S.C. 103(a) as being unpatentable over Linkwitz et al USPN 6,295,469 in view of Keusch et al USPN 4,989,607 and Gross USPN 5,380,272. Link et al teaches the use of Lidocaine and epinephrine in a reservoir (see example I for instance) that includes EDTA and sodium metabisulfite in various polymers including PVP, polyvinyl alcohol (see column 4 lines 45+ and example I) with a first electrode 71 and a second 72 that are considered to be a single electrode assembly. Applicant differs in reciting the polymer is crosslinked and that the device is prepackaged as an assembly. Keusch et al teach the advantages of crosslinked PVP

for emitting drugs in an iontophoresis device including using it for adhesion to the skin. Gross (figure 9) teaches prepackaging of both counter and working electrodes was well known in the art. To have used the crosslinked PVP of Keusch as a substitute for its disclosed benefits as the gel in the Linkwitz et al device would have been obvious. To have prepackaged the device as a "ready to use" assembly would have been well known and apparent to those of ordinary skill. Alternatively, to have used the Lidocaine epinephrine compositions in crosslinked PVP matrices as reservoirs in the Gross device would have been obvious in view of Linkwitz and Keusch.

The examiner notes that the effective filing date for claims 54-55, 58, 60-68 (i.e. those not containing new matter) is 6-9-1999, i.e. the parent file where the first time packaging is mentioned.

Claims 58-59 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linkwitz et al USPN 6,295,469 in view of Keusch et al USPN 4,989,607 and Gross USPN 5,380,272 as applied to claims 54-57, 60-66 above, and further in view of Sage, Jr. et al USPN 5,334,138.

Applicant differs from the collective teachings of Linkwitz et al., Keusch et al and Gross in reciting the use of glycerin as a solvent additive which was well known - see column 5 lines 30-35 of Sage, Jr when applying Lidocaine in PVA as well as other matrices (see column 5 line 62-68).

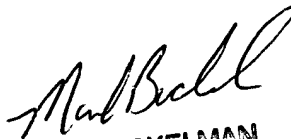
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

April 15, 2004

  
MARK BOCKELMAN  
PRIMARY EXAMINER